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09/830,915	05/02/2001	Jennifer L Hillman	PF-0633 USN	5225

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,915	HILLMAN ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1,2 and 15-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed August 2, 2004. Currently, claims 1-20 are pending. Claims 1-2, 15-20 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election traverse of Group I, claims 3-14, SEQ ID NO: 12 and 29 in the paper filed August 2, 2004 is acknowledged.

The response asserts that the polypeptides and the nucleic acids exhibit corresponding special technical features. This argument has been thoroughly reviewed, but is not found persuasive because the claims encompass fragments of polypeptides which may encompass single amino acids or the nucleic acids encoded by the single amino acids. There is no special technical feature over the art for nucleic acids encoding a single amino acid (see Brennan rejection below).

Further, as noted by the most recent International Search and Preliminary Examination Guidelines (in force as of January 1, 2004, page 98), the guidelines provide that where an alternative DNA claim was presented that encompassed a DNA molecule that did not encode protein X (such as Claim 3, 4, 5, 9, 10, 11 in the instant application), some Authorities might find that the claims did not share the same or corresponding technical feature and therefore lacked unity. The guidelines specifically provide examples with fragment language, and hybridization language. Therefore, Example 17, Part 2 of the Annex B to the PCT Administrative instructions appears to have been clarified such that the situation is nonanalogous to the instant situation.

The response asserts that a search of 10 polynucleotide sequences does not create an undue burden. This argument has been thoroughly reviewed, but is not found persuasive because each of the sequences is patentably distinct and a search of SEQ ID NO: 1 is not coextensive of SEQ ID NO: 2. Thus there is a burden of search for all 10 of the sequences. However, since this is a 371 application and the standard of lack of unity applies and has been argued by the response, since there is no special technical feature which links them, burden is not applicable to 371 applications. 371 applications are subject to the lack of unity requirements.

Claims 1-2, 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 1-2, 15-20 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application is a 371 of PCT/US99/26048, filed November 4, 1999. The application also claims priority to several provisional applications.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Drawings

4. The drawings are acceptable.

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 3-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to an isolated and purified polynucleotide encoding a polypeptide consisting of SEQ ID NO: 12 and fragments thereof. The claims are also

drawn to 90% identity and hybridization language. Finally, the claims are drawn to a nucleic acid comprising SEQ ID NO: 29 and fragments thereof.

The specification teaches the nucleic acid encoding SEQ ID NO: 12 is a human membrane transport protein (MTRP-12)(page 5). The specification teaches that the MTRP may be used for diagnosis, treatment, prevention of membrane transport disorders, immune/inflammatory disorders and cell proliferative disorders. The specification asserts functional assays to demonstrate MTRP activity (page 54). However, there is no teachings of what constitutes MTRP activity. In Figure 2, page 62, the specification provides signature sequences which includes sulfate transporter signature and asserts homologies to transporters from human and mouse. The GI numbers were typed into NCBI website, however, no results were obtained, as the database said that the numbers were not available.

The post filing date art teaches that SEQ ID NO: 29 is 99.9% identical to the human solute carrier family 26, member 6 mRNA disclosed by Strausberg (Genbank Accession Number BC017697, October 6, 2003). SEQ ID NO: 29 is 2580 nucleotides in length, nucleotides 1-2580 correspond to nucleotides 19-2598 of Strausberg.

The post-filing date art discusses the cloning and characterization of SLC26A6 as a novel member of the solute carrier 26 gene family (see Waldegger et al. Genomics, Vol. 72, pages 43-50, 2001). The SLC26 gene family comprises 5 mammalian genes that encode anion transporter-related proteins. As seen in Table 1, SLC26A1 (aka SAT-1), SLC26A2, SLC26A3, SLC26A4, SLC26A5 and SLC26A6 are not all associated with the same disease. For example three human members have

been identified and associated with specific genetic disease, namely DTD, diastrophic dysplasia; CLD, congenital chloride diarrhea; PDS, Pendred syndrome. It is clear that not all members of the family are associated with the same diseases (see Table 1, page 44). Further SLC26A6 did not reveal anion transport activity with tracer uptake to intracellular pH measurements (abstract). As seen in the comparison in Figure 1, the SLC26A6 does not have a box to indicate the sulfate transporter signature, therefore appears to lack a sulfate transporter signature. Lohi et al. (Genomics, Vol. 70, pages 102-112, 2000) also provides a comparison and characterization of SLC26A6. As seen in Table 1, pages 104, the family of genes are each expressed in different sites and are associated with different diseases. The post filing date art also discusses the Slc26a6 which comprises alternative splicing of the second exon to generate two distinct isoforms, denoted Slc26a6a and Slc26a6b. Xie (Genbank Accession Number AF416721, September 11, 2002) teaches a nucleic acid human SLC26A6a anion exchanger mRNA. The nucleic acid is 99.8% identical to the instant SEQ ID NO: 29. Nucleotides 1-2580 of SEQ ID NO: 1 correspond to nucleotides 18-2597 of Xie with three mismatches over the entire length.

Utility must be established at the time of filing, rather than after the invention has been completed. Neither the prior art nor the specification provides a specific or substantial utility for the claimed sequences, fragments, 90% identical sequences or sequence which hybridize to the sequences. With respect to a well-established utility, there is no art of record that discloses or suggests any activity for the claimed nucleic acid prior to the filing date. The specification asserts that the MTRP nucleic acids may

be used for diagnosis, treatment, prevention of membrane transport disorders, immune/inflammatory disorders and cell proliferative disorders. The instant specification has not asserted a specific utility. A specific utility is a utility that is specific to the subject matter that is claimed. The specification fails to provide a specific disease, disorder or condition for diagnosis or treatment or prevention. There is a list that spans over a page an a half of the instant text that the specification suggests that may be used for. This is not specific to any particular one of the diseases within the laundry list of diseases. A general statement of diagnostic utility, such as diagnosing an unspecified disease, would be insufficient absent a disclose or what specific condition can be diagnosed.

A substantial utility is a utility that defines a "real world" use. The instant specification asserts that MTRP may be used for diagnosis, treatment, prevention of membrane transport disorders, immune/inflammatory disorders and cell proliferative disorders. Each of these asserted utilities require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and are not substantial utilities. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved do not define a "substantial utility." Utility must be established at the time of filing of the application. The instant specification fails to identify the instant nucleic acid within the SLC26 gene family. However, it is clear from the post filing date art, that at the time the invention was made and even in 2002, the utility of the claimed nucleic acids is unclear. The post filing date art clearly indicates that SLC26A6 which is 99.9% identical to the instant SEQ

ID NO: 29 was not associated with any disease. The post filing date art also clearly teaches that the solute carrier 26 gene family does not share a common function. The post-filing date are teaches that each of the genes in the family are directed to different transport anions. SLC26A6 did not reveal anion transport activity with tracer uptake or intracellular pH measurements (see Waldegger, abstract). Moreover, Lohi characterizes the members of the SLC26A family to be divergent in expression and transport nature. Thus, it is clear that not all members of the family act in the same manner.

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Thus, the instant claims are drawn to a polynucleotides which lacks a well-established or specific and substantial utility.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3-14 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted

utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 3-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated and purified polynucleotide encoding a polypeptide consisting of SEQ ID NO: 12 and fragments thereof. The claims are also drawn to 90% identity and hybridization language. Finally, the claims are drawn to a nucleic acid comprising SEQ ID NO: 29 and fragments thereof.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of

nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. As provided in the written description guidelines, Example 7, the single species, namely SEQ ID NO: 29 encompasses full-length genes and cDNAs that are not described. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 29 is only a fragment of any full-length gene or cDNA species. Weighing all factors, 1) partial structure of the DNAs that comprise SEQ ID NO: 29, 2) breadth of the claims as reading on genes yet to be discovered in 3) the lack of correlation between the structure and function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 29. Applicant has not disclosed any genomic DNA sequences and particularly has not disclosed any intron sequences or regulatory sequences. Accordingly, Applicants have not adequately disclosed the

relevant identifying characteristics of a representative number of species within the claimed genus.

With respect to claims which encompass allelic variations. As provided in Example 11, no common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 29 alone is insufficient to describe the genus. There is no description of the mutational sites that exist in nature and there is no description of how the structure of SEQ ID NO: 29 relates to the structure of any strictly neutral alleles. The general knowledge in the art concerning variants does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is such that they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

The claims are also directed to sequences which minimally encompass fragments. The specification and the claims fail to describe a representative number of nucleic acids which minimally comprise a fragment of SEQ ID NO: 29. It is clear from the post filing date art, that the claims encompass nucleic acids which where not in the

possession of applicant at the time the invention was made. A fragment has not been limited by the specification or the claims. Fragments may encompass a single nucleotide embedded within a larger sequence such that every nucleic acid which comprised a "T" would be encompassed by the claims.

Finally, the claims are drawn to hybridization language. Example 9 of the written description guidelines states that a structure function relationship with hybridization language may satisfy the written description guidelines. The instant claims do not provide a structure function relationship with hybridization language. Therefore, the hybridization language would encompass sequences from other species, mutated fragment sequences, allelic variants, splice variants, genomic sequences and so forth.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 3-7, 9-11 rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796, December 12, 1995).

Brennan teaches oligonucleotides having 10 nucleotides each (10-mers). The oligonucleotides represent every possible permutation of the 10-mer oligonucleotide. Moreover, Brennan teaches a matrix of all possible 3 mers. The three mers encode a fragment of the polypeptide of Claim 1, as they encode for an amino acid (see Figure 1). Therefore, Brennan teaches an isolated polynucleotide encoding a fragment of SEQ ID NO: 12.

10. Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers (Genbank Accession Number G15083, January 1996).

Myers teaches a nucleic acid sequence tagged site which comprises a fragment of SEQ ID NO: 29, namely nucleotides 2366-2565 of SEQ ID NO: 29 are 99.5% identical with nucleotides 206-7 of the nucleic acid of Myers. The database teaches an "N" rather than a "G." The genomic DNA comprises both the target and the complement. Myers teaches each limitation of the instant claims.

Conclusion

11. **No claims allowable.**

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

J. Goldberg

Jeanine Goldberg
Patent Examiner
September 3, 2004